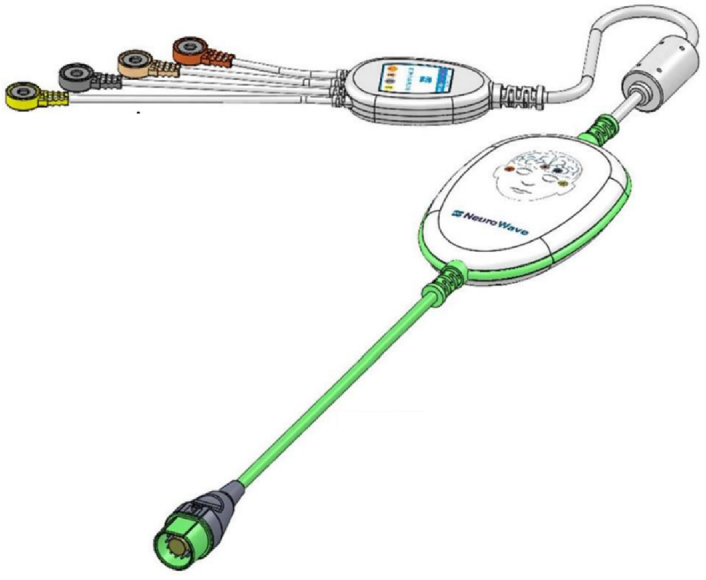
NeuroWave
HARNESSING THE POWER OF EEG

NeuroSENSE®Advanced EEG Module

Model: NM-901e

- USER MANUAL -



Rx only

Federal (USA) law restricts this device to sale by or on the order of a physician.

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NeuroSENSE Advanced EEG Module (NM-901e) User Manual
P/N: 960-7401-DOC-02

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Introduction and Contact

The NeuroSENSE® Advanced EEG Module (Model: NM-901e) is a medical device designed to operate with compatible Host Patient Monitors.

This manual is intended for medical personnel, researchers, and biomedical engineering personnel to provide guidance on the proper installation, operation, and cleaning of the NeuroSENSE Advanced EEG Module. Keep this manual in a convenient location in the vicinity of the NeuroSENSE Advanced EEG Module.

This manual does not intend, nor can it be relied upon, to provide for every event that can happen during installation, operation, or maintenance of the NeuroSENSE EEG Module. If additional questions arise, please direct them to:

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Indications for Use

The NeuroSENSE Advanced EEG Module (Model: NM-901e) is intended for monitoring the brain state of patients 18 years of age and older in the operating room and other clinical settings by acquiring electroencephalographic (EEG) signals.

The WAV_{CNS} Index, a quantifier of EEG activity calculated by the NeuroSENSE EEG Module may be used as an aid in monitoring the hypnotic effect of anesthetics. The anesthetics include inhaled anesthetics and propofol in combination with opioids. The NeuroSENSE Module is intended to be used under the direction and interpretation of a qualified medical professional.

Validation of the WAV_{CNS} algorithm was performed in a randomized-controlled clinical trial in 75 surgical patients (age: 18 to 71 years, male/female: 18/57). Anesthesia was induced with propofol/remifentanil and maintained with desflurane and supplemental doses of fentanyl as needed. The study confirmed that the WAV_{CNS} index distinguishes consciousness from unconsciousness during induction of anesthesia and emergence from anesthesia, and that it also correlates with randomized changes in inhaled anesthetic endtidal concentration during maintenance of anesthesia.

The generated EEG signals are not affected by the artifact detection and/or removal algorithms. The EEG waveforms are output as acquired after user-selected display filters, which may be available on a compatible Host Patient Monitor, are applied.

Contra-indications

The NeuroSENSE Advanced EEG Module Model: NM-901 should never be used as the sole basis for clincal assessment of the patient's state or guiding anesthetic management. The device is intended for use as a supplement to standard anesthesia care only. The NeuroSENSE EEG Module readings should always be interpreted using clinical judgement and training, within the context of the clinical situation and in conjunction with other clinical signs.

The NeuroSENSE Advanced EEG Module is not intended for use in patients younger than 18 years of age or in environments outside clinical settings.

Other contraindications include skin conditions and physiognomy that preclude the application of electrodes on the patient's forehead. Do not place the electrodes on the patient's forehead if they cannot be safely and correctly placed.

[LB.10102] - WAV_{CNS} VALUES SHOULD BE INTERPRETED CAUTIOUSLY WITH CERTAIN ANESTHETIC COMBINATIONS, E.G., USE OF EITHER KETAMINE OR NITROUS OXIDE WITH NARCOTICS TO PRODUCE UNCONSCIOUSNESS. THE NEUROSENSE READINGS SHOULD ALSO BE INTERPRETED WITH CAUTION IN PATIENTS WITH KNOWN NEUROLOGICAL PATHOLOGY OR SEIZURE ACTIVITY, OR THOSE TAKING PSYCHOACTIVE MEDICATIONS. OTHER CONTRAINDICATIONS INCLUDE SKIN CONDITIONS AND PHYSIOGNOMY THAT PRECLUDE APPLICATION OF ELECTRODES ON THE PATIENT'S FOREHEAD. DO NOT PLACE THE ELECTRODES ON THE PATIENT'S FOREHEAD IF THEY CANNOT BE SAFELY AND CORRECTLY PLACED.

[LB.10104] - LIKE WITH ANY MONITORED PARAMETER, ERRONEOUS PROCESSED EEG VALUES MAY OCCUR DUE TO CERTAIN ARTIFACTS AND CONDITIONS (E.G., EXCESSIVE EYE OR FACIAL MUSCLE ACTIVITY: HEAD AND BODY MOVEMENTS; MOVEMENT OR DAMAGE OF PATIENT CABLE, ELECTRODES OR ELECTRODE LEADS; STRONG OR UNUSUAL ELECTROMAGNETIC INTERFERENCE; BAD (HIGH-IMPEDANCE) SKIN CONTACT (E.G., DUE TO PROFUSE SWEATING OR TEARING); USE OF NON-RECOMMENDED OR EXPIRED ELECTRODES AND INCORRECT ELECTRODE PLACEMENT OR CONNECTION).

[LB.10113] - THE NEUROSENSE ADVANCED EEG MODULE IS MR UNSAFE. IT MUST NOT BE USED IN AN MRI ENVIRONMENT.

General Description of the NeuroSENSE Monitoring System

The NeuroSENSE Advanced EEG Module is a medical device for brain function monitoring in the operating room and other clinical settings designed to work with a compatible Host Patient Monitor. The NeuroSENSE EEG module acquires and processes brain waves or electroencephalogram (EEG) signals obtained from noninvasive electrodes placed on a patient's forehead. The EEG is collected from 2 frontal, bilateral EEG channels so as to monitor independently both brain hemispheres. The processed EEG variables are continuously calculated by the module, and both raw and processed EEG data are sent to a compatible Host Patient Monitor for display and interpretation by a qualified medical professional and for use as a supplement to the anesthesia standard of care. The proprietary processed variable, WAV_{CNS} (Wavelet-based Anesthetic Value for Central Nervous System), quantifies the patient's brain activity as affected by anesthetic drugs.

Theory of Operation

The brain is the target organ of anesthetic drugs, while the EEG is a noninvasive measurement of brain cortical activity. Most general anesthetics produce dose-dependent suppression of neuronal activity within the CNS, and consequently alter cortical activity and induce unconsciousness in a dose-dependent manner [1]. The NeuroSENSE EEG Module calculates a number of processed EEG variables to quantify the levels of a patient's brain activity based on continuous, noninvasive EEG measurements.

Using a wavelet-based decomposition of the EEG signal and a statistical function for information extraction, the NeuroSENSE EEG Module calculates a proprietary quantitative descriptor of the central nervous system, referred to as WAV_{CNS} (see **White Paper**, downloadable from NeuroWave's website, for published articles and references on WAV_{CNS}). Wavelet analysis is a powerful signal processing technique for non-stationary signals such as EEG. The unique and proprietary application of this technique allows the NeuroSENSE EEG Module to track without delay the changes in the patient's brain status. This is done by continuously calculating the WAV_{CNS} and other processed EEG variables, based on 1-second epochs from a single-channel EEG signal, and displaying them on a screen of a Host Patient Monitor.

Independent processed EEG variables including WAV_{CNS} indices are calculated and displayed for 2 frontal, bilateral EEG channels, one per brain hemisphere. The NeuroSENSE readings may be used as an aid in monitoring the hypnotic effect of certain anesthetics on the brain of adult patients, and are to be interpreted by a qualified medical professional.

For improved reliability, the NeuroSENSE EEG Module employs algorithms for automatic detection and removal of physiological and environmental artifacts that commonly contaminate EEG signals. Also, the module has built-in circuitry for detection and minimization of interference due to electro-surgical units. The module also performs self-tests, automatic calibration of the amplifiers and continuous check of the electrode-skin contacts to ensure proper operation and optimal signal quality.

Processed Variables

The NeuroSENSE Advanced EEG Module calculates and outputs the following processed

1. With increasing blood-drug concentration, the EEG signal evolves from a low-amplitude, large-bandwidth, noise-like signal, to a higher amplitude signal with slower waves. If a large amount of anesthetic is given, the cortical activity completely disappears, resulting in an isoelectric or flat signal.

variables for each of the 2 frontal, bilateral EEG channels:

— The current WAV_{CNS} value
— Suppression Ratio (SR)
— Electromyogram (EMG)
— Density Spectral Array (DSA)

The processed variables are described in detail in Chapter 5.

In addition, the following are output by the module:

— Two EEG waveforms in real time and at all times
— Information about signal alerts, artifacts, notifications and errors
— Signal Quality indicators

WAV_{CNS} Guidelines

The WAV_{CNS} (Wavelet-based Anesthetic Value for Central Nervous System) Index is a proprietary EEG index calculated by the NeuroSENSE Advanced EEG Module. This processed EEG variable may be used as an aid in monitoring the hypnotic effect of certain anesthetics on patients 18 years of age and older. It is a number ranging from 0 to 100, where values near 100 indicate a fully awake state, while values near 0 represent a fully suppressed EEG with no substantial activity (flat EEG). An appropriate range for the WAV_{CNS} index during general anesthesia has been established to be between 40 and 60. The WAV_{CNS} values within this range correspond to a low probability of a patient being either conscious or exhibiting significant burst suppression [2] indicative of deep anesthesia.

The WAV_{CNS} Index is calculated independently and simultaneously for 2 frontal, bilateral EEG channels corresponding to each brain hemisphere. In the absence of unilateral brain pathology and with good signal quality, the level of agreement between the WAV_{CNS} Indices for the left and right cerebral hemispheres is typically within ±8 units with a negligible bias.

[LB.10105] - PRONOUNCED INTER-HEMISPHERIC ASYMMETRY MAY OCCUR DUE TO CERTAIN ENVIRONMENTAL, PHYSIOLOGICAL OR PATHOLOGICAL FACTORS (E.G., PRESENCE OF ARTIFACTS, STRONG ELECTROMAGNETIC INTERFERENCE, BILATERAL DIFFERENCE IN FACIAL MUSCLE ACTIVITY, BILATERAL DIFFERENCE IN THE AMOUNT OF FULLY SUPPRESSED EEG ACTIVITY, UNILATERAL BRAIN PATHOLOGY, ETC.)

[LB.10106] - IN SITUATIONS WHERE THE TWO BILATERAL WAV_{CNS} INDICES EXHIBIT A LARGE DIFFERENCE INDICATING DIFFERENT DEPTHS OF ANESTHESIA, CLINICAL ASSESSMENT OF THE PATIENT'S STATE AND ANESTHETIC MANAGEMENT SHOULD STRICTLY BE BASED ON CLINICAL JUDGEMENT, WITHIN THE CONTEXT OF THE CLINCIAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.

2. Burst suppression is defined as periods of flat EEG separated by periods of fast and large amplitude activity. The NeuroSENSE Advanced EEG Module calculates the Suppression Ratio (SR) to help in assessing deep anesthesia. The SR value represents the amount of time with suppressed EEG epochs within the last minute. SR is displayed as a number within a range of 0-100%. For the purpose of establishing the WAV_{CNS} guidelines, significant burst suppression was considered to correspond to SR values greater than 40%.

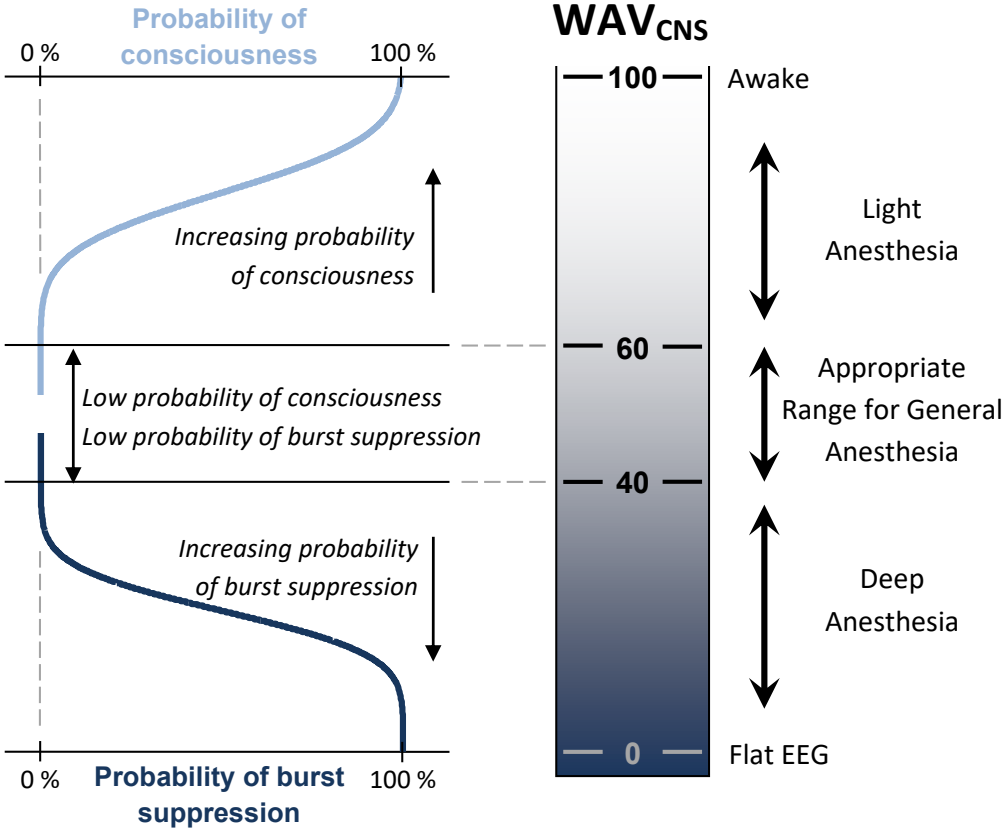


Figure 1: WAV_{CNS} Scale. An appropriate WAV_{CNS} range for general anesthesia is between 40 and 60 since within this range there is a very low probability of a patient being either awake or in deep anesthetic state as characterized by the presence of significant burst suppression (SR $>$ 40%).

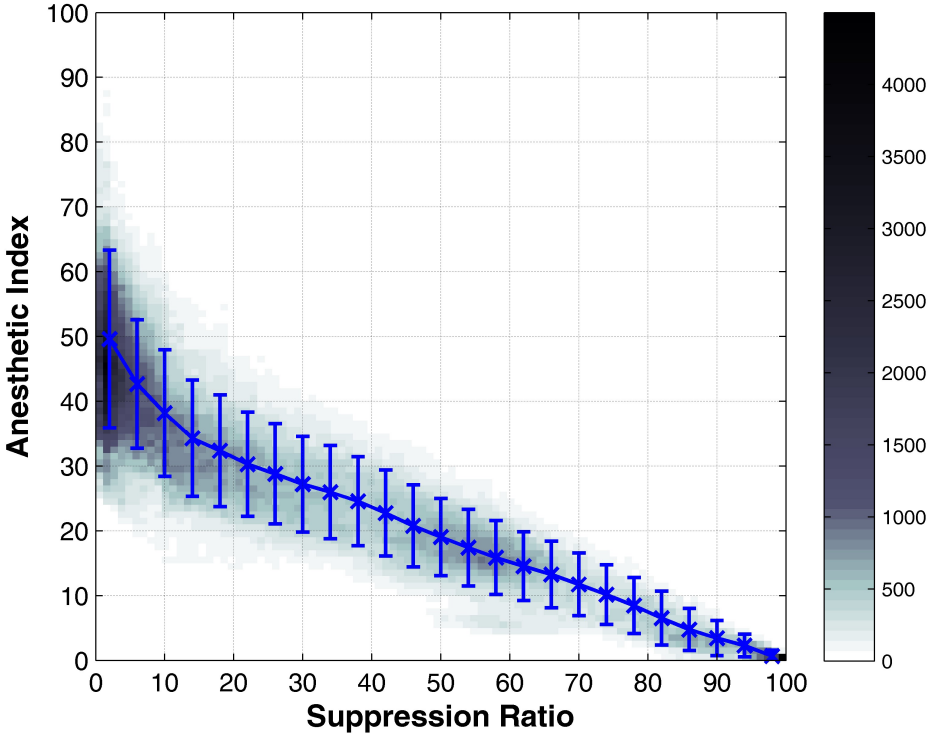


Figure 2: Relationship (density plot and mean±std) between WAV_{CNS} anesthetic index and suppression ratio (SR). Deep anesthetic states are characterized by the presence of significant burst suppression.

System Overview

Figure 3 depicts the NeuroSENSE Advanced EEG Module and its components and accessories that are briefly described below:

NeuroSENSE Advanced EEG Module (Model: NM-901e)
: The NeuroSENSE EEG Module collects the EEG signals through the patient cable connected to the electrodes placed on the patient's forehead, digitizes the acquired signals and calculates processesd EEG variables. Raw EEG signals and processed EEG variables are continuously sent via the data cable to the Host Patient Monitor for display.

NeuroSENSE EEG Electrode Kit (Model: EK901e) (sold separately)
: The NeuroSENSE EEG Electrode Kit is an accessory that contains the disposable electrodes and skin preparation materials. The packaging in the electrode kit guides the user on how to prepare the patient's skin and where to place the electrodes.

Host Patient Monitor
: A compatible 3rd-party Monitor is required to serve as the Host Patient Monitor for the NeuroSENSE EEG Module and to display the module's outputs. Contact NeuroWave Systems to obtain a list of compatible host monitors, and refer to their Operator's Manual.

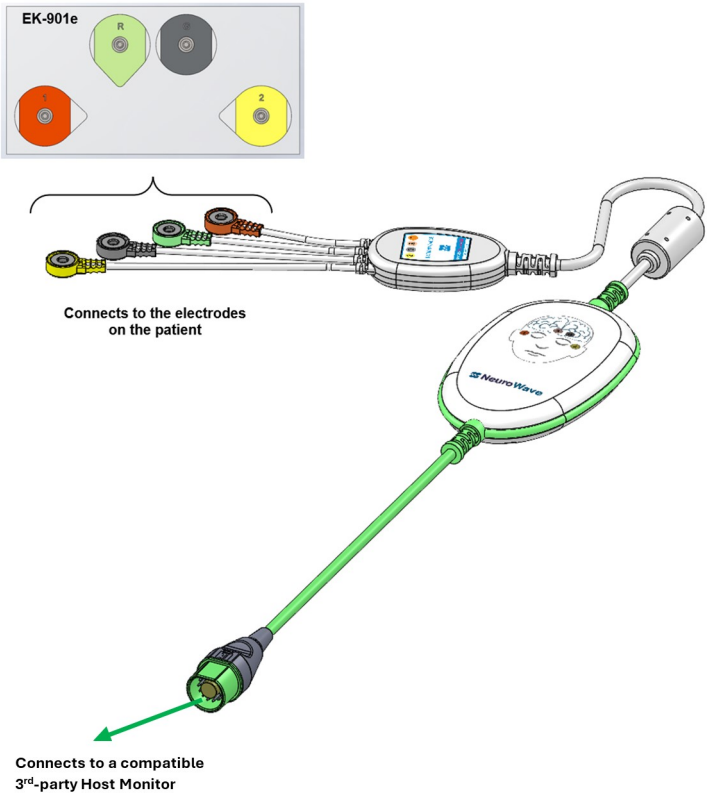


Figure 3: NeuroSENSE Advanced EEG Module.

Chapter 1

Safety Precautions

Read this section thoroughly before operating the NeuroSENSE Advanced EEG Module. In addition, do not use this device unless it has been installed, operated and maintained, as instructed by this user manual. The following symbols and terms will be used throughout this manual:

Symbol	Name	Definition
	**WARNING**	A warning advises against actions that could result in injury to the operator, patient, or others. **WARNINGS WILL ALWAYS BE WRITTEN IN ALL CAPS AND BOLD.**
	CAUTION	A caution advises against actions that could lead to damage or malfunction of the NeuroSENSE Advanced EEG Module, although injury to the operator, patient, or others is unlikely. CAUTIONS WILL ALWAYS BE WRITTEN IN ALL CAPS.
	*Note*	A note provides supplemental information that may clarify a procedure or allow a user to adapt device settings for their personal needs. *Notes will always be written in italic.*

1.1 WARNINGS

[LB.10101] - **THE NEUROSENSE ADVANCED EEG MODULE IS INTENDED FOR USE AS A SUPPLEMENT TO STANDARD ANESTHESIA CARE. THIS DEVICE SHOULD NEVER BE USED AS THE SOLE BASIS FOR CLINICAL ASSESSMENT OF THE PATIENT'S STATE OR GUIDING ANESTHETIC MANAGEMENT. THE NEUROSENSE READINGS SHOULD ALWAYS BE INTERPRETED USING CLINICAL JUDGEMENT AND TRAINING, WITHIN THE CONTEXT OF THE CLINICAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.**

[LB.10102] - **WAV_{CNS} VALUES SHOULD BE INTERPRETED CAUTIOUSLY WITH CERTAIN ANESTHETIC COMBINATIONS, E.G., USE OF EITHER KETAMINE OR NITROUS OXIDE WITH NARCOTICS TO PRODUCE UNCONSCIOUSNESS. THE NEUROSENSE READINGS SHOULD ALSO BE INTERPRETED WITH CAUTION IN PATIENTS WITH KNOWN NEUROLOGICAL PATHOLOGY OR SEIZURE ACTIVITY, OR THOSE TAKING PSYCHOACTIVE MEDICATIONS. OTHER CONTRAINDICATIONS INCLUDE SKIN CONDITIONS AND PHYSIOGNOMY THAT PRECLUDE APPLICATION OF ELECTRODES ON THE PATIENT'S FOREHEAD. DO NOT PLACE THE ELECTRODES ON THE PATIENT'S FOREHEAD IF THEY CANNOT BE SAFELY AND CORRECTLY PLACED.**

[LB.10103] - **THE NEUROSENSE ADVANCED EEG MODULE IS NOT INTENDED FOR USE IN PATIENTS YOUNGER THAN 18 YEARS OF AGE OR IN ENVIRONMENTS OUTSIDE CLINICAL SETTINGS.**

[LB.10104] - **LIKE WITH ANY MONITORED PARAMETER, ERRONEOUS PROCESSED EEG VALUES MAY OCCUR DUE TO CERTAIN ARTIFACTS AND CONDITIONS (E.G., EXCESSIVE EYE OR FACIAL MUSCLE ACTIVITY: HEAD AND BODY MOVEMENTS; MOVEMENT OR DAMAGE OF PATIENT CABLE, ELECTRODES OR ELECTRODE LEADS; STRONG OR UNUSUAL ELECTROMAGNETIC INTERFERENCE; BAD (HIGH-IMPEDANCE) SKIN CONTACT (E.G., DUE TO PROFUSE SWEATING OR TEARING); USE OF NON-RECOMMENDED OR EXPIRED ELECTRODES AND INCORRECT ELECTRODE PLACEMENT OR CONNECTION).**

[LB.10105] - PRONOUNCED INTER-HEMISPHERIC ASYMMETRY MAY OCCUR DUE TO CERTAIN ENVIRONMENTAL, PHYSIOLOGICAL OR PATHOLOGICAL FACTORS (E.G., PRESENCE OF ARTIFACTS, STRONG ELECTROMAGNETIC INTERFERENCE, BILATERAL DIFFERENCE IN FACIAL MUSCLE ACTIVITY, BILATERAL DIFFERENCE IN THE AMOUNT OF FULLY SUPPRESSED EEG ACTIVITY, UNILATERAL BRAIN PATHOLOGY, ETC.)

[LB.10106] - IN SITUATIONS WHERE THE TWO BILATERAL WAV_{CNS} INDICES EXHIBIT A LARGE DIFFERENCE INDICATING DIFFERENT DEPTHS OF ANESTHESIA, CLINICAL ASSESSMENT OF THE PATIENT'S STATE AND ANESTHETIC MANAGEMENT SHOULD STRICTLY BE BASED ON CLINICAL JUDGEMENT, WITHIN THE CONTEXT OF THE CLINCIAL SITUATION AND IN CONJUNCTION WITH OTHER CLINICAL SIGNS.

[LB.10107] - THE NEUROSENSE ADVANCED EEG MODULE HAS BEEN DESIGNED TO PROMOTE PATIENT SAFETY. THE MODULE IS TYPE BF DEFIBRILLATOR PROOF AND IS PROTECTED AGAINST THE EFFECT OF DEFIBRILLATOR DISCHARGE AND MAY REMAIN ATTACHED TO THE PATIENT. NEUROSENSE READINGS SHOULD BE INTERPRETED WITH CAUTION DURING CARDIAC DEFIBRILLATION. A TYPICAL RECOVERY TIME FOLLOWING EXPOSURE TO CARDIAC DEFIBRILLATION VOLTAGE IS 2 SECONDS.

[LB.10108] - DO NOT REUSE ELECTRODES. DISCARD AFTER EACH USE.

[LB.10109] - DO NOT CONNECT ANY OTHER EQUIPMENT TO THE NEUROSENSE EEG ELECTRODES. AVOID CONTACT OF THE NEUROSENSE EEG MODULE WITH OTHER EQUIPMENT AND OBJECTS DURING OPERATION.

[LB.10110] - THE ELECTRODES MUST NOT BE POSITIONED BETWEEN THE DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT.

[LB.10111] - CARE SHOULD BE TAKEN WHEN POSITIONING THE CABLES TO AVOID PATIENT STRANGULATION, OTHER BODILY INJURY OR TRIPPING HAZARDS. CARE SHOULD BE TAKEN WHEN USING THE DEVICE IN POSITIONS WITH LIMITED ACCESS TO LEADS AND ELECTRODES, SUCH AS IN PRONE OR LATERAL DECUBITUS POSITIONS, SINCE THIS MAY LEAD TO PRESSURE TRAUMA ON EYES AND FACE. WHENEVER LEADS OR ELECTRODES ARE BEING OBSCURED, ENSURE THEY ARE ROUTED AWAY FROM THE EYES AND THE PATIENT'S HEAD/FOREHEAD IS SECURED IN SUCH A WAY TO AVOID EXCESSIVE PRESSURE BEING APPLIED TO EYES OR FACE BY THE LEADS OR ELECTRODES.

[LB.10112] - DO NOT USE THE NEUROSENSE ADVANCED EEG MODULE WHERE CONCENTRATIONS OF FLAMMABLE GASSES MAY OCCUR. THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE. EXPLOSION HAZARD: INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

[LB.10113] - THE NEUROSENSE ADVANCED EEG MODULE IS MR UNSAFE. IT MUST NOT BE USED IN AN MRI ENVIRONMENT.

[LB.10114] - USE GENERAL PRECAUTIONS IN ORDER TO AVOID CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. IF THIS HAPPENS, CLEAN THOROUGHLY THE NEUROSENSE EEG MODULE AND ITS CABLES ACCORDING TO THE CLEANING INSTRUCTIONS IN THIS MANUAL. IN THE CASE OF CONTAMINATED ELECTRODES, DISCARD THEM ACCORDING TO YOUR STANDARD PRACTICE FOR BIOHAZARD MATERIALS AND USE NEW ONES.

[LB.10115] - DISCONNECT THIS EQUIPMENT FROM THE HOST PATIENT MONITOR BEFORE CLEANING. DO NOT USE LIQUID OR SPRAY DETERGENTS. USE A DAMP CLOTH. DO NOT USE AND/OR MIX CLEANING SOLUTIONS THAT MAY RESULT IN HARMFUL GASES AND PERSONAL INJURY.

[LB.10116] - DO NOT AUTOCLAVE THE NEUROSENSE EEG MODULE AND ITS INTEGRATED CABLES. THIS WILL DAMAGE THE ELECTRONICS AND MAY LEAD TO INJURY TO THE OPERATOR OR PATIENT. THIS WILL ALSO VOID THE WARRANTY.

[LB.10117] - THE NEUROSENSE ADVANCED EEG MODULE SHOULD BE CHECKED BY QUALIFIED TECHNICAL PERSONNEL IF ANY OF THE FOLLOWING SITUATIONS ARISES:
- LIQUID IS SUSPECTED TO HAVE PENETRATED INTO THE EQUIPMENT;
- THE EQUIPMENT HAS BEEN EXPOSED TO EXCESSIVE MOISTURE;
- THE EQUIPMENT DOES NOT WORK WELL, OR YOU CANNOT GET IT TO WORK ACCORDING TO THE USER MANUAL;
- THE EQUIPMENT HAS BEEN DROPPED AND DAMAGED; AND
- THE EQUIPMENT HAS BEEN EXPOSED TO SEVERE MECHANICAL SHOCK OR HAS OBVIOUS SIGNS OF BREAKAGE.

[LB.10118] - KEEP THIS EQUIPMENT AWAY FROM HUMIDITY THAT EXCEEDS THE LIMITS SPECIFIED IN THE USER MANUAL.

[LB.10119] - DO NOT PULL ON THE CABLES OF THE NEUROSENSE ADVANCED EEG MODULE AS THIS MAY RESULT IN THE HOST PATIENT MONITOR TIPPING OVER.

[LB.10120] - **DO NOT REMOVE THE NEUROSENSE ADVANCED EEG MODULE PROTECTIVE ENCLOSURE. NEVER OPEN THE EQUIPMENT. INJURY TO THE OPERATOR OR DAMAGE TO THE EQUIPMENT COULD OCCUR. THIS COULD ALSO COMPROMISE IP RATING FOR WATER INGRESS.**

[LB.10121] - **PERIODICALLY (I.E., SEMI-ANNUALLY) CHECK THE LEAKAGE CURRENTS TO ENSURE THAT THEY COMPLY WITH THE LIMITS SET BY APPLICABLE SAFETY STANDARDS (I.E., IEC 60601-1). IN CASE OF AN EVENT SUCH AS SPILLAGE OF BLOOD, SALINE FLUID OR OTHER LIQUID OCCURS, OR AFTER A MAJOR ELECTRICAL POWER SURGE, RE-TEST BEFORE FURTHER USE.**

[LB.10122] - **THIS EQUIPMENT PERFORMS CONTINUOUS IMPEDANCE MEASUREMENT TO THE ELECTRODES IN ORDER TO CHECK THAT THE ELECTRODES ARE IN GOOD CONTACT WITH THE SKIN. THE INJECTED MEASUREMENT SIGNAL AT 165 HZ COULD INTERFERE WITH OTHER MEDICAL EQUIPMENT CONNECTED TO THE PATIENT OR OTHER NEUROMONITORING DEVICES SUCH AS EEG/AUDITORY EVOKED POTENTIALS MONITORS. THIS MEASUREMENT CAN BE DISABLED IF NEEDS BE.**

[LB.10123] - **DO NOT SUBMERSE IN LIQUIDS THE NEUROSENSE EEG MODULE AND ITS INTEGRATED PATIENT AND DATA CABLES.**

[LB.10124] - **DO NOT CONNECT THE NEUROSENSE EEG MODULE TO A MONITOR OTHER THAN COMPATIBLE MONITORS LISTED IN THIS MANUAL.**

1.2 CAUTIONS

[LB.10201] - THE NEUROSENSE ADVANCED EEG MODULE SHOULD ALWAYS BE USED ACCORDING TO THE INSTRUCTIONS SET FORTH IN THIS MANUAL. DO NOT OPERATE THE NEUROSENSE EEG MODULE BEFORE READING AND UNDERSTANDING THIS MANUAL. DO NOT OPERATE THE DEVICE UNLESS IT HAS BEEN PROPERLY INSTALLED AS INSTRUCTED IN THIS MANUAL. IMPROPER USAGE MAY LEAD TO PERSONAL INJURY OR DEVICE DAMAGE.

[LB.10202] - 50/60 HZ INTERFERENCE FROM OTHER DEVICES IN CLOSE PROXIMITY TO THE NEUROSENSE ADVANCED EEG MODULE AND/OR TO ITS PATIENT CABLE AND ELECTRODES COULD LIMIT THE AVAILABILITY OF THE PROCESSED EEG INFORMATION. CARE SHOULD BE TAKEN TO AVOID PLACING THE NEUROSENSE EEG MODULE CLOSE TO HIGH POWERED DEVICES SUCH AS HEATERS. PROPER ROUTING OF ELECTRODE LEADS AWAY FROM SUCH DEVICES COULD SIGNIFICANTLY HELP REDUCE THE LEVEL OF THE INTERFERENCE FROM THE MAINS.

[LB.10203] - THE NEUROSENSE ADVANCED EEG MODULE COMPLIES WITH IEC 60601-1-2 REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY. IF THIS SYSTEM AFFECTS OR IS AFFECTED BY OTHER EQUIPMENT IN ITS PROXIMITY DUE TO ELECTRO-MAGNETIC INTERFERENCE, TRY THE FOLLOWING:
- INCREASE THE DISTANCE BETWEEN SYSTEMS,
- RE-ARRANGE SYSTEM CABLING,
- USE SEPARATE OUTLET CIRCUIT BRANCHES FOR POWERING THE SYSTEMS.

[LB.10204] - NEUROSENSE EEG MODULE READINGS SHOULD BE INTERPRETED WITH CAUTION WHEN THE TRAIN-OF-FOUR STIMULATOR IS IN USE.

[LB.10205] - AVOID EXPOSING THE NEUROSENSE EEG MODULE TO SUDDEN TEMPERATURE CHANGES THAT CAN LEAD TO CONDENSATION WITHIN THE DEVICE. ALWAYS ALLOW SUFFICIENT TIME FOR THE CONDENSATION TO EVAPORATE BEFORE PLACING THE DEVICE INTO OPERATION.

[LB.10206] - CARE SHOULD BE TAKEN WHEN POSITIONING THE CABLES TO AVOID DAMAGE CAUSED BY STEPPING ON THEM OR POSITIONING/MOVING OTHER MEDICAL EQUIPMENT OVER THEM.

[LB.10207] - DO NOT PLACE THE NEUROSENSE EEG MODULE OR ITS CABLES ON ANY MOVING OR VIBRATING SURFACE AS THIS CAN LEAD TO POOR SIGNAL QUALITY. IN CASE OF MECHANICAL VIBRATIONS OF THE NEUROSENSE EEG MODULE AND/OR ITS INTEGRATED CABLES, PROCESSED EEG READINGS SHOULD BE INTERPRETED WITH CAUTION.

[LB.10208] - THE NEUROSENSE ADVANCED EEG MODULE IS DESIGNED TO OPERATE WITH THE NEUROSENSE EEG ELECTRODES. THE USE OF ELECTRODES NOT RECOMMENDED BY NEUROWAVE IS HIGHLY DISCOURAGED AS IT MAY REDUCE THE SIGNAL QUALITY AND INTERFERE WITH THE CALCULATION OF EEG PROCESSED VARIABLES.

[LB.10209] - NEUROWAVE CANNOT GUARANTEE, BE LIABLE FOR, OR BE RESPONSIBLE FOR USE OF THE NEUROSENSE EEG MODULE WITH ELECTRODES OR ELECTRODE SYSTEMS OTHER THAN THOSE RECOMMENDED BY NEUROWAVE SYSTEMS INC.

[LB.10210] - DO NOT OPEN THE NEUROSENSE EEG ELECTRODE KIT UNTIL READY FOR USE. THE ELECTRODE GEL COULD DRY OUT, CAUSING HIGH ELECTRODE IMPEDANCE. THERE IS ALSO A RISK OF CONTAMINATION OF THE ELECTRODES.

[LB.10211] - THE ADHESION OF THE ELECTRODES MAY BECOME LOOSE AND THE ELECTRODE-SKIN CONTACT MAY DEGRADE IF PATIENT IS SWEATING OR TEARING PROFUSELY. IN ADDITION, NEUROSENSE EEG MODULE READINGS SHOULD BE INTERPRETED WITH CAUTION IF PATIENT IS SWEATING PROFUSELY.

[LB.10212] - USE ONLY MODERATE FORCE WITH ELECTRODE PREP PAD, OTHERWISE SKIN IRRITATION MAY OCCUR.

[LB.10213] - THE NEUROSENSE ADVANCED EEG MODULE SHOULD BE CHECKED BY QUALIFIED TECHNICAL PERSONNEL IF EXPOSED TO A SEVERE MECHANICAL OR THERMAL SHOCK, WHICH MAY IMPACT NORMAL OPERATION AND/OR SAFETY INCLUDING WATER INGRESS PROTECTION RATING. IN CASE OF VISIBLE DAMAGE OR LOSS OF NORMAL OPERATION, CONTACT NEUROWAVE FOR SERVICING.

[LB.10214] - THIS USER MANUAL SHOULD BE KEPT IN CLOSE PROXIMITY TO THE NEUROSENSE ADVANCED EEG MODULE AT ALL TIMES.

[LB.10215] - DISCONNECT THIS EQUIPMENT FROM THE HOST PATIENT MONITOR BEFORE CLEANING. DO NOT USE LIQUID OR SPRAY DETERGENTS. USE A DAMP CLOTH. DO NOT USE AND/OR MIX CLEANING SOLUTIONS THAT MAY RESULT IN HARMFUL GASES AND PERSONAL INJURY.

[LB.10216] - DO NOT ATTEMPT TO OPEN, MODIFY, OR REPAIR THE NEUROSENSE EEG MODULE OR ITS INTEGRATED PATIENT AND DATA CABLES. INJURY TO THE OPERATOR OR DAMAGE TO THE EQUIPMENT COULD OCCUR. THIS COULD ALSO COMPROMISE IP RATING FOR WATER INGRESS. CONTACT NEUROWAVE FOR SERVICING. ALL REPAIRS MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL.

[LB.10217] - THE NEUROSENSE EEG MODULE WILL NOT BE ABLE TO ASSESS SIGNAL QUALITY WHEN THE CONTINUOUS IMPEDANCE CHECK IS DISABLED. IN THIS CASE, IT IS RECOMMENDED TO PERIODICALLY PERFORM THE ON-DEMAND ELECTRODE CHECK.

[LB.10218] - DO NOT PLACE THE NEUROSENSE EEG ELECTRODES BETWEEN THE SURGICAL SITE AND THE RETURN ELECTRODE OF THE ELECTRO-SURGICAL UNIT. THIS WILL MINIMIZE THE HAZARD OF BURNS IN CASE OF A DEFECT IN THE HIGH- FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION. ALSO, DO NOT PLACE THE NEUROSENSE EEG ELECTRODES BETWEEN THE ELECTRODES OF ANY ENERGY DELIVERING DEVICE (E.G., BRAIN STIMULATION DEVICES).

[LB.10219] - NEUROSENSE EEG MODULE READINGS SHOULD BE INTERPRETED WITH CAUTION DURING THE ELECTRO-CONVULSIVE SHOCK THERAPY (ECT). ALSO, ECT PADS SHOULD NOT COME IN CONTACT WITH THE NEUROSENSE ELECTRODES. IN CASE OF INTERFERENCE, TRY TO RESOLVE IT BY INCREASING THE DISTANCE BETWEEN THE NEUROSENSE EEG ELECTRODES AND ECT PADS.

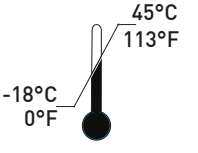
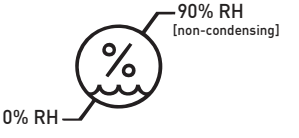
[LB.10220] - DO NOT CONNECT THE NEUROSENSE EEG MODULE TO ANYTHING OTHER THAN A COMPATIBLE HOST MONITOR (CONTACT NEUROWAVE SYSTEMS FOR THE LIST OF COMPATIBLE MONITORS).

[LB.10221] - IF TAMPERING OF THE NEUROSENSE EEG MODULE IS SUSPECTED, TAKE THE DEVICE OUT OF SERVICE. IF NO TAMPERING IS FOUND FOLLOW THE ERROR HANDLING INSTRUCTIONS CONTAINED IN THIS USER MANUAL.

[LB.10222] - THE DEVICE SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE DEVICE SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

1.3 Device Symbols Key

Serial Number	
Model Number	
Manufacturer	
European Authorized Representative	
Medical Device	
By Prescription Only	
See User Manual / Instructions for Use	 
Batch Code	
Use by Date	
Defibrillator-proof Type BF Equipment	
MR Unsafe	

CE Marking	CE
IPX Water Ingress Protection Rating	**IPX4**
Latex-free Product	
PVC-free Product	
Do Not Reuse	
Do Not Use If Product is Damaged	
Recycle: Electronic Equipment	
Maximum 24 Hours of Usage	
Storage Temperature Limits	
Storage Humidity Limits	
Storage Atmospheric Pressure Limits